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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/652,334	08/28/2003	Stuart Peltz	54569.8003.US03	5532

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EXAMINER	
RAMIREZ, DELIA M	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 05/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/652,334	PELTZ ET AL.	
	Examiner	Art Unit	
	Delia M. Ramirez	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 5-41 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 5-41 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Claims 5-41 are pending.

Applicant's submission of a preliminary amendment canceling claims 5-41 in a communication filed on 8/28/2003 is acknowledged.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 5-6, drawn to a ribozyme which acts as an antagonist or agonist of translation termination, classified in class 435, subclass 91.31.

II. Claims 5-6, drawn to an antisense molecule which acts as an antagonist or agonist of translation termination, classified in class 531, subclass 23.1.

III. Claims 5-6, drawn to a ligand which acts as an antagonist or agonist of translation termination, classified in class 530, subclass 350.

IV. Claims 7-8, drawn to a multiprotein complex, classified in class 530, subclass 350.

V. Claims 9-11, drawn to an antibody which binds a multiprotein complex, classified in class 530, subclass 387.1.

VI. Claims 12 and 15, drawn to an agent which binds to a multiprotein complex, unclassifiable as no physical characteristics have been defined to allow classification.

VII. Claim 13, drawn to an agent which inhibits or modulates the binding of human MTT1 to eRF3 or MTT1 to a polysome, unclassifiable as no physical characteristics have been defined to allow classification.

VIII. Claims 14 and 16, drawn to an antisense molecule which facilitates binding of human MTT1 to eRF3 or MTT1 to a polysome, classified in class 536, subclass 23.1.

IX. Claims 14 and 16, drawn to a ribozyme which facilitates binding of human MTT1 to eRF3 or MTT1 to a polysome, classified in class 435, subclass 91.31.

X. Claim 17, drawn to a method of modulating peptidyl transferase activity during translation with a multiprotein complex, classified in class 435, subclass 4.

XI. Claims 18-20, drawn to a method of modulating peptidyl transferase activity during translation with an agent which binds a multiprotein complex, classified in class 435, subclass 4.

XII. Claims 21-25, drawn to a method for screening for a drug using a multiprotein complex, classified in class 530, subclass 350.

XIII. Claim 26, drawn to a method of modulating the efficiency of translation termination of mRNA and/or degradation of aberrant transcripts with a multiprotein complex, classified in class 530, subclass 350.

XIV. Claim 27, drawn to a method for identifying a disease involving a defect in a multiprotein complex, classified in class 424, subclass 9.1.

XV. Claims 28-30, drawn to a method to treat a disease by administering a multiprotein complex or an agent which binds to a multiprotein complex, classified in class 514, subclass 2.

XVI. Claim 31, drawn to a method for identifying a disease involving a defective multimeric protein, classified in class 424, subclass 9.1.

XVII. Claims 32-41, drawn to a method of identifying genes involved in modulation of translation termination using the motifs disclosed in SEQ ID NO: 1-9, classified in class 436, subclass 9.

The inventions are distinct, each from the other because of the following reasons:

2. Groups I-IX each comprise a chemically unrelated structure capable of separate manufacture, use, and effect. The ribozymes in Groups I and IX, and the antisense molecules in Groups II and VIII each comprises an unrelated nucleic acid sequence, whereas the proteins of Groups III, IV and V each comprise an unrelated amino acid sequence. The agents of Groups VI-VII are undefined agents which can be chemical or biological compounds, and while the agent of Group VI can be the antibody of Group V, the agent can also be a compound with a totally unrelated chemical structure. The nucleic acids of Groups I, II, VIII and IX do not encode the proteins of Groups III, IV, and V. Furthermore, the nucleic acids of Groups I and IX have catalytic activity whereas the nucleic acids of Groups II and VII do not. The proteins from Groups III and IV can be used also in therapeutic or diagnostic methods, in addition to raise the antibodies of Group V. The proteins of Groups III, IV and V cannot be prepared from recombinant expression of the nucleic acids of Groups I, II, VIII and IX.

3. Inventions IV, X, XII-XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the multiprotein complex of Invention IV can be used in the different methods of Inventions X or XII-XV as well as to elicit antibodies.

4. Inventions VI, XI and XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the agent of Invention VI can be used in the different methods of Inventions XI and XV. Furthermore, if the agent of Invention VI were to be a protein, it can also be used to elicit antibodies.

5. Inventions I-III, V, VII-IX and X-XVII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the products of Inventions I-III, V, VII-IX are neither used nor made by the methods of Inventions X-XVII.

6. Inventions X-XVII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of Inventions X-XVII comprise different steps, may use different products and produce different results.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, as shown by their different classification, restriction for examination purposes as indicated is proper.

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

9. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and

process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement can be traversed (37 CFR 1.143).

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

12. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 872-9306. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from

either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
May 14, 2004

PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600